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Sunlamp Products; Performance Standard

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 1002 and 1040

[Docket No. 75N-0047]

Sunlamp Products; Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule establishes a performance standard for sunlamp products and ultraviolet lamps intended for use in these products. The standard is intended to reduce the possibility of sunlamp-related injury by reducing unnecessary exposure and overexposure to sunlamp radiation by: (1) Limiting shorter wavelength emissions that are necessary and pose unreasonable risk, (2) providing for more adequate label warnings and user instructions containing safety information, and (3) requiring special lamp bases, protective goggles, timers, and controls to help users limit the duration and amount of exposure. A sunlamp product would be subject to these requirements if it is an electronic product designed to use one or more ultraviolet lamps (bulbs) and is intended for irradiation of any part of the living human body by ultraviolet radiation within a specified range of wavelengths to induce skin tanning. Ultraviolet lamps subject to the standard are those which produce radiation within a prescribed range of wavelengths and are intended for use in sunlamp products.

EFFECTIVE DATE: May 7, 1980, for sunlamp products that are manufactured on or after this date.

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SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 30, 1977 (42 FR 65189), the Food and Drug Administration (FDA) proposed to establish a radiation safety performance standard for sunlamp products due to a recognized need for a regulatory standard for such products to protect the public health and safety. Interested persons had until February 28, 1978, to file written comments on the proposal. Comments were received from at least 214 different sources: 169 individuals, 26 physicians and medical facilities, 11 medical associations and their chapters, 9 manufacturers, 4 governmental agencies, a manufacturer's association, an equipment rental association, a spa owner, a retail sales company, and an independent quality control laboratory. Also, there were four congressional inquiries.

A summary of the comments and the agency response are as follows:

1. Several comments expressed the idea that the safety performance standard is needless, ineffective, costly, and an unwarranted government intrusion. Others maintained that: (1) Most sunlamp products already come with adequate warnings, (2) the public is already aware of ultraviolet radiation hazards, and (3) only those who are careless are injured by sunlamp products.

That there is a radiation problem with sunlamps is shown by the large number of sunlamps-related skin and eye injuries treated annually in hospital emergency rooms. This number does not include injuries treated outside the hospital or any long-term effects, such as skin cancer. FDA has considered the increased costs that a performance standard may impose on manufacturers and, therefore, on consumers of sunlamp products, and is convinced that the costs are out-weighed by the increased safety that will result from the standard. (See the economic impact assessment that accompanied the proposed regulation.) Furthermore, changes introduced in the final rule will reduce the cost of complying with the standard.

The standard for sunlamp products is being established to protect the consumer from acute burns (as evidenced by erythema) and exposure to unnecessary, hazardous radiation (in this case, ultraviolet C), and to warn the consumer of the adverse effects to the body after exposure to ultraviolet radiation. A consumer can take appropriate action: (1) When informed of the possible adverse effects to the body of exposure to ultraviolet radiation, and (2) when the product is provided with necessary safety performance features. The safety information and performance features on the product may be ineffective when a person is careless. However, the agency believes sunlamps perform a function desired by the consumer and, consequently, has not penalized the prudent individual by removing this potentially hazardous product from the marketplace.

2. Several comments objected to the standard's proposed early effective date of only 30 days after the date of publication of the final rule. Some objections were based upon the technical problems associated with the redesign of products; others were based on the technical, logistic, and personnel problems of manufacturing sunlamp products that would comply with the standard. Also, a manufacturer claimed that, because its sunlamp product now conforms to the provisions of the proposed rule, the urgency for the early effective date has been eliminated.

The agency agrees with the intent of these comments and defers the effective date of the standard to 180 days after the date of publication of the final rule. The effective date has not been deferred to more than 180 days after the date of publication because many companies have already redesigned many aspects of their products to meet the standard and because the high injury rate continues.

3. A comment stated that there are millions of existing sunlamps now in use that require medium screw base replacement bulbs. Those manufacturers who are marketing Underwriter Laboratories, Inc., listed products have already changed (since 1975) to designs requiring other than medium screw bases. For the older devices, however, an immediate cut-off of replacement lamps would seem an unfair economic burden to the owners. A reasonable approach would be to defer the effective date of this portion of the standard for 12 to 18 months.

The agency notes that products manufactured before the effective date of an applicable regulation would not be subject to that regulation. Replacement lamps for old products can be manufactured until the effective date of the standard and may be sold thereafter until the supply is exhausted. Further, the effective date of the standard is being deferred to 180 days after publication of the final rule.

4. One comment concerned the length of time a sunlamp must comply with the performance standard. The comment stated that experience confirms that timers and other parts of the sunlamp may fail prematurely because of faulty design, and, therefore, manufacturers should provide FDA with reasonable assurances of the reliability of the timers and other components used in their products.

The agency notes that the manufacturer of a radiation emitting electronic product subject to a performance standard is required to certify to the purchaser that the specific product being purchased complies throughout the useful life of the product with the applicable requirements of the standard in effect at the date of manufacture. The manufacturer must also develop a suitable quality control

program and assure the FDA of compliance through reports describing the product and the quality control program. In addition, the agency has a program of inspecting the manufacturing facilities for regulated products.

5. One comment objected to the introduction of the language, "or otherwise affect the function of the body," and the specific exclusion of prescription ultraviolet products from the proposed definition of "sunlamp product." The comment argued that this changes the standard substantially from one only for sunlamps used for skin tanning. Furthermore, the comment objected to the classification, or at least implication of classification, of sunlamp products as medical devices, and it objected to applying Part 801 (21 CFR Part 801) to such products until they have been properly classified in accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c), added by the Medical Device Amendments of 1976 (Pub. L. 94–295).

The agency accepts a portion of this comment because the standard was developed specifically for sunlamps used in skin tanning and may not be appropriate for ultraviolet devices intended for other applications, e.g., cabinets used exclusively for psoriasis treatment. Therefore, the definition of "sunlamp product" in § 1040.20(b)(9) is revised to delete the language "or otherwise affect the structure or any function of the body" and the reference to Part 801. The agency believes sunlamp products are medical devices because the various therapeutic uses for sunlamp products, including treatment of fungal diseases, vitamin D production, treatment of psoriasis, and treatment of acne, cannot be readily separated from the tanning function insofar as assurance of intended use and danger from overexposure are concerned. Thus, the references to Part 801 in § 1040.20(b)(1) and (d) are retained.

The agency notes that the last sentence in proposed § 1040.20(b)(9) identifying uses not covered by the definition of "sunlamp product" is not needed to clarify the definition and, therefore, also deletes it in this final rule.

6. Several comments questioned the appropriateness of applying the standard to the sunlamp facilities installed in gyms, health clubs (spas), and other similar commercial establishments, where conditions of operation vary widely. For example, the comments alleged that timers are unnecessary when trained attendants are present or ineffective when more than one person is using the sunlamp facility at the same time. One comment recommended that commercial facilities be encouraged to hire attendants rather than rely on timers or customers to follow posted instructions. One national health club stated that virtually none of its sunrooms conforms to the proposed standard and that extensive and expensive modifications would be necessary to bring these facilities up to the standard. The comment explained further that, in most cases, there are no timers, no devices to interrupt manually the sunlamp operation, no user instructions, and no protective eyewear. Furthermore, the comment stated, the club is considering removing the sunlamp facilities from use until it is sure the facilities are safe to prevent any liability through noncomplying equipment.

The agency believes that, in the interest of the public health, the standard should apply to any sunlamp product meeting the definition of § 1040.20(b)(9), including those in use in commercial facilities. The agency has, however, considered the various requirements of the final rule as applied to these suntanning facilities, and to sunlamp products generally, and has concluded that the timer requirements of § 1040.20(c)(2) may be inappropriate in some circumstances. Upon application by the manufacturer, other means for providing radiation safety or protection may be approved in accordance with procedures in § 1010.4 for granting variances.

FDA advises that only sunlamp products, including commercial suntanning facilities, manufactured after the effective date of the final rule will be subject to the standard. Thus, owners of existing commercial suntanning facilities need not modify their facilities to comply with the standard, although they are encouraged to do so. Also, because in response to another comment the agency has concluded that fluorescent ultraviolet lamps may continue to be designed to fit the medium bipin lampholder, no retrofit programs by the commercial suntanning facilities will be necessary to accommodate the available replacement lamps (see comment 14). Some changes in procedures may be needed to ensure the availability of eyewear and the availability of information about the hazards associated with exposure of the body to ultraviolet radiation. These changes will make the facilities safer but not completely safe, because there may be no safe threshold level for exposure to ultraviolet radiation.

7. Some comments objected to the irradiance ratio of 0.001 in § 1040.20(c)(1). One objection was on the ground that the manufacturer had attempted and failed to design an efficacious bare quartz lamp that would meet this requirement. Another manufacturer claimed that the ultraviolet radiation in the wavelength range of 200 through 260 nanometers (nm) is less hazardous than the radiation in the wavelength range of 260 through 320 nm. It was stated that, because the latter is allowed, the former need not be restricted too much, and an irradiance ratio of 0.02 should be adopted.

The agency declines to raise the irradiance ratio on the basis presented in these comments. The radiation in the wavelength range of 200 through 260 nm is known to be hazardous and is not necessary for skin tanning. Available data on terrestrial solar irradiances indicate that radiation of that wavelength range emitted by the sun does not reach the earth. The relative safety of the ultraviolet radiation of the wavelength range from 200 through 260 nm and the ultraviolet radiation of the wavelength range from 260 through 320 nm is not the issue. The fact is that ultraviolet radiation in the shorter wavelength range is both hazardous and unnecessary for skin tanning, and, therefore, exposure to it should be reduced.

8. A comment recommended the adoption of 0.003 as the irradiance ratio in § 1040.20(c)(1) to take into account product variability and uncertainties in irradiance measurements for quality control in the manufacturing environment.

FDA agrees. Achievement of an exact ratio of 0.001 is not easy. Product variability and uncertainties of measurement of irradiance ratios render achievement of the 0.001 irradiance ratio difficult. Because many presently available sunlamps are close to the 0.001 irradiance ratio but not exactly at it, they would require substantial redesigning to lower their levels of ultraviolet radiation of wavelengths less than 260 nm. Achievement of a 0.003 irradiance ratio, however, is much easier for all concerned.

Also, the agency believes that the increase in the irradiance ratio will not compromise the protection afforded the public (1) because lamps that have little filtration for the ineffective ultraviolet radiation wavelenghts less than 260 nm will still be prohibited; (2) because uncertainties in determining compliance will cause manufacturers to produce a product with a target irradiance substantially below 0.003; and (3)

because the level of ultraviolet radiation of wavelengths less than 260 nm will be increased at most only 2 parts in 1,000 of the total ultraviolet emission. Furthermore, the cost of many sunlamps on the market will not be increased as a result of a necessary product redesign to meet the new irradiance ratio limit. For these reasons, the irradiance ratio is increased to 0.003.

9. A comment suggested that the irradiance ratio be abolished because it does not accomplish the desired effect of limiting the integrated irradiance at shorter wavelengths to less than 0.1 milijoule per square centimeter (mJ/cm^2) or any other value that might be considered appropriate. The comment stated that, because the bioeffects literature shows that "0.1 mJ/cm^2 at 254 nm may have deleterious effects," the regulation should simply limit the permitted total integrated irradiance for all wavelengths less than 260 nm to less than 0.1 mJ/cm^2 within the maximum timer interval possible for each sunlamp product. This eliminates specifying a maximum timer interval. The requirement of a timer that has a specified accuracy would still be relevant while the suggested change would permit the manufacturer to choose the rate at which its product achieves the desired tanning and should give the consumer a reasonable choice of products.

The agency agrees with the bioeffects literature; however, it rejects the conclusion because an upper limit to the integrated irradiance for the short wavelength ultraviolet only would require that each sunlamp product model have different ultraviolet radiation filtration and timer characteristics, depending upon the lamp brightness and distance of the user from the product. The irradiance ratio in § 1040.20(c)(1) would avoid these problems, provide greater design flexibility to manufacturers, and reduce the short wavelength range ultraviolet emissions. The irradiance ratio limit is intended only to limit unnecessary, hazardous radiation and is not to be understood as a biologically "safe" limit. A manufacturer is free to choose the rate at which the product achieves the desired tanning regardless of whether a specific irradiance limit for the ultraviolet radiation of wavelengths less than 260 nm or an irradiance ratio is chosen.

10. Several comments questioned how the 10-minute maximum timer interval was established and claimed that 10 minutes may be too much in some cases and too little in others. They stated that the warmup time should be defined as the time taken to reach a certain irradiance level and that the maximum timer interval should be increased by the warmup time. Also, they stated that the minus tolerance on timer accuracy was not needed and should not be required. Another comment was concerned that, because sunlamp manufacturers usually recommend a set of exposure distances and corresponding exposure times, the agency might regard the recommended exposure time for the shortest distance as the maximum timer interval.

The agency advises that the preamble to the December 1977 proposal discussed at length the basis on which the upper time limit was established. The purpose of having a maximum interval for the timer is to reduce the chance of severe erythema whereby medical attention is necessary. A 10-minute maximum timer interval was selected as one that would provide adequate protection and effectiveness when used with currently available sunlamps. This timer interval is consistent with the Underwriters Laboratory Standard (UL–482), and it also takes into account the lamp warmup time. The concept of graded timer interval was considered earlier, but it was not adopted because it would be more complex and, therefore, more difficult to implement.

The agency believes that both negative and positive error limits for the maximum timer interval are necessary for scale accuracy to deliver a desired exposure to the user. The consumer must have confidence in the timer scale for all time intervals less than 10 minutes. Also, the agency believes that the maximum timer interval should correspond to the maximum exposure time recommended by the manufacturer or to 10 minutes, whichever is less. Therefore, § 1040.20(c)(2)(ii) is issued as proposed.

11. One comment stated that the requirement for an extra manual control (switch) to activate the lamp (§ 1040.20(c)(4)) is unnecessary because, unless the timer resets itself automatically, the cumulative exposure time could not exceed 10 minutes.

The agency considers manual control for the resumption of radiation emission to be a necessary safety feature because better user control of exposure time is provided. The means that the manufacturer may use for implementing this performance criterion are not established by the requirement, and a separate switch per se for resumption of radiation is not required. The control features in § 1040.20(c) (2), (3), and (4) may all be built into the timer. Alternatively, the manufacturer may use any other configuration of timer and switches to meet these requirements. Section 1040.20(c)(4) is clarified to include explicitly the applicability of the requirement to timers.

12. The preamble to the December 1977 proposal encouraged comments concerning the transmission of visible radiation through protective eyewear. Several comments stated that the protective eyewear required in proposed § 1040.20(c)(5) should transmit enough visible light to enable the user to read the labels, set the timer, and perform other critical functions. Other comments stated that 2 percent transmission of visible light, as proposed in § 1040.20(c)(5)(ii), was too low a value for adequate vision. Also, several comments suggested that the language of the Underwriters Laboratory Standard (UL–482) paragraph 14.3, be used. This states: "The goggle lenses shall allow sufficient transmission of visible light emitted from the sunlamp to enable the user to see clearly enough to reset the timer in a darkened room."

The agency agrees that the protective eyewear should transmit enough visible radiation to allow the user of the product to see to perform critical functions in a darkened room. The proposed specific upper limit of 0.02 for spectral transmittance of the protective eyewear for radiation of wavelengths greater than 360 nm is arbitrary. Therefore, § 1040.20(c)(5)(ii) is changed to be consistent with the Underwriters Laboratories requirement for transmission of visible radiation through the protective eyewear. However, as a guide, the protective eyewear should not transmit hazardous levels of visible radiation when the wearer looks directly toward the lamp from the minimum use distance.

13. One comment objected to the requirement that multiple sets of protective eyewear be supplied if the manufacturer recommends that a sunlamp be used by more than one person at a time (§ 1040.20(c)(5)(i)), because extra sets of eyewear are offered for sale if the customer believes they will be needed. The comment asserted that the effect of the requirement will be increased consumer prices with no corresponding benefit because many users already have protective eyewear.

The agency regards the requirement of § 1040.20(c)(5)(i) as useful and consistent with the agency's desire to provide to the users the performance features they need to reduce the radiation hazard from sunlamps. This is especially true when the manufacturer recommends that the product be used by more than one person at a time. Further,

a would-be purchaser of a sunlamp product would not necessarily have protective eyewear. The comment is rejected.

14. There were many strongly worded objections to the proposal from dermatologists and from people afflicted with psoriasis. Their objections were directed primarily to proposed § 1040.20(c)(6)(iii), which would have prohibited any lamps subject to the standard from fitting a "medium bipin" lampholder described in the national consensus standard issued by the American National Standards Institute (ANSI C81.20–1976). The comments claimed that, if the proposed rule were promulgated, the leading manufacturer of fluorescent sunlamps (which fit the medium bipin lampholder) might cease producing them, and the result would be great hardship for many who use fluorescent sunlamps for the treatment of dermatological disorders such as psoriasis.

The agency is sympathetic to these comments and does not desire to have the fluorescent sunlamp removed from the market. Nor was that the intent of the proposal. The rule applies to sunlamps used for tanning; it is not intended to apply to fluorescent sunlamps used for medical treatment of dermatological disorders or for industrial or agricultural uses. Proposed § 1040.20(c)(6) is intended to prevent use of tanning sunlamps in lampholders used for general illumination that are commonly accessible to users at home and other places. Thus, it would ensure that sunlamps are used only in fixtures with appropriate timers, controls, and warning labels.

Revised sales and marketing information supplied by the leading manufacturer of fluorescent sunlamps in its comments on the proposal indicates that the annual sales volume of fluorescent sunlamps is about 31,000 units, of which 1 percent are used for skin-tanning purposes and 1 percent for medical prescription purposes in the home; 68 percent are used in health clubs, gymnasiums, etc.; and 30 percent are used in hospitals, in medical practice, and for industrial and agricultural purposes. Therefore, the proposed § 1040.20(c)(6)(iii) would have only a small effect upon the safety performance of sunlamp products used in the home, but would impose excessive retrofitting costs upon existing commercial suntanning, medical, industrial and agricultural facilities when the sales distribution of fluorescent sunlamps is considered. The agency has concluded that the benefit of the proposed provision does not offset the disadvantages. Thus, the requirement that an ultraviolet lamp may not be capable of insertion and operation in the medium bipin lampholder is deleted from the final order.

15. Several comments objected to the quantity and the repetitiveness of the information required by §§ 1010.2, 1010.3, 1040.20 (d) and (f), and Part 801 for the ultraviolet lamp, sunlamp product, and user instructions. Some comments noted that ultraviolet lamps are of special concern because it may be impossible to put all of the required information on the lamps. Others noted that the printing on a lamp is nearly invisible when the lamp is operating. One manufacturer suggested that labeling requirements for ultraviolet lamps be deleted entirely and that appropriate warnings in accompanying instructions be suggested in the preamble of the final regulation. Other manufacturers suggested simplified warning statements for the products. One comment stated that mere repetition of any required warning statements would generally be ineffective.

The agency believes that users of a sunlamp product and ultraviolet lamps should have the information necessary to make informed decisions regarding the risks of using the product. This principle requires appropriate product labeling and instructions for use.

The agency believes, however, that the amount of information originally proposed to be on the ultraviolet lamp can be reduced and the mode of display simplified without compromising public health and safety. The requirement of a label for certification and a label for the name and address of the manufacturer (21 CFR 1010.2 and 1010.3) can be satisfied by having tags or labels containing the information permanently affixed on the packaging for each lamp, if the name of the manufacturer and date of the manufacture are on the lamp for purposes of identification. The name of the manufacturer and the date of manufacture appearing on the lamp may be shortened by use of a code or symbols if the manufacturer has supplied the Director, Bureau of Radiological Health, with the key to the code or symbols and the location of the information on the lamp. Thus, the introductory text of § 1040.20(d) is changed and a new § 1040.20(d)(3) is added to incorporate these less restrictive concepts.

The agency also believes that the information required by the final rule to be on the sunlamp product is the minimum needed for the user to make informed decisions concerning the risks and proper use of the lamp in the absence of user instructions. User instructions can be more extensive and more detailed, at the option of the manufacturer. There is no certainty that the user instructions provided under § 1040.20(f) will always be with the product. Also, the publication of suggestions for the content of users' instructions in the preamble of the final rule is not appropriate. After publication, the preamble is not retained as part of the regulation in the Code of Federal Regulations (CFR). The information required by § 1040.20(d)(1) is not redundant to that required to be on the ultraviolet lamp (§ 1040.20(d)(2)). Thus, the comments objecting to the sunlamp product label requirements are rejected.

16. Several comments on § 1040.20(d)(1)(i) stated that all skin cancer tests have been performed with broad spectral sources and that the erythemal wavelengths alone are responsible for skin cancer. The comments stated that the fluorescent sunlamp has a relatively narrow spectral distribution, and there is no evidence that skin cancer has been caused by a fluorescent sunlamp. The comments expressed concern that reference to skin cancer could lead to unjustified litigation that would place the responsibility for any skin cancer on a sunlamp product and not on the other causes that cannot be identified.

The agency rejects the comment. The wavelength range of the radiation emitted by a fluorescent sunlamp is included in the wavelength ranges that are known to be associated with the induction of skin cancer. Radiation of erythemal wavelengths is also present in solar radiation, which is known to be associated with the appearance of skin cancer although the detailed action spectrum for cancer production in the ultraviolet region of the spectrum is not known. The inference that cancers are induced only in the presence of ultraviolet radiation of broad spectral distribution and not by radiation in the narrower erythemal spectrum has not been demonstrated. Therefore, this reference to skin cancer is justified, and the required warning is retained in this final rule.

17. Several comments on proposed § 1040.20 (d) and (f) concerned the harshness of required labels and instructions and asserted that no skin cancer has ever been observed in humans that could be attributed to the use of sunlamps, while agreeing that exposure of the skin to natural sunlight over many years can cause skin cancer. The comments expressed particular

difficulty in understanding why FDA is insisting on the reference to cancer when it has not seen fit to impose any reference to cancer in labeling of cigarettes. One manufacturer suggested that, if caution labels and instructions along these lines are needed, then the concept of repeated overexposure should be added because there is no link to the harmful effects from just "exposure" to sunlamp radiation. Another manufacturer urged that the similarity of sunlamp radiation to that of the sun be emphasized. Alternative wording of some of the warning statements was suggested. Another comment stated that the wording in § 1040.20(f) (1) and (2) and the repetition of the warning, as required, will unfairly alarm people and will deter the use of sunlamps.

The agency notes that sunlamps can produce erythema and that radiation of erythemal wavelength is present in solar radiation, which is known to be associated with the appearance of skin cancer. Warning labels and instructions for sunlamp products are necessary when the hazards of exposure to ultraviolet radiation are considered. Also, the label required by § 1040.20(d)(1)(i) warns the user of the similarity between sunlamp radiation and solar radiation. The overexposure to ultraviolet radiation in a single incident leads to acute effects such as skin burn and eye irritation (photokeratitis). Repeated exposure (chronic) may lead to premature skin aging and cancer. The warning labeling and instructions are believed to be sufficient. The agency also believes that the wording of the labels is accurate and understandable, so that the majority of the readers will comprehend the significance of the warnings. Finally, the agency advises that the health aspects of cigarettes and the appropriate warning labeling are not the subject of this particular agency action. The comments do not justify a change in the regulation and are rejected.

18. A comment stated that phrases such as "minimum use distance" and "recommended maximum exposure time" are ambiguous because exposure sequence, skin sensitivity, and customer use vary considerably. In contrast, flexibility in the writing of instructions would result in greater customer awareness of any recommended precautions. The comment urged that § 1040.20(d)(1) be revised to eliminate the discussed phrases.

The agency notes that both "minimum use distance" and "maximum exposure time" are defined in § 1040.20(b) and are values recommended by the manufacturer of each sunlamp product. A recommended value for "minimum use distance" and "maximum exposure time" is useful, for example, for the person being exposed for the first time after a long interlude or for the sensitive person but should not be relied upon by persons suffering from diseases such as xeroderma pigmentosum, erythropoietic porphyria, or lupus erythematosis. The "minimum use distance" and "maximum exposure time" are required to be specified by the manufacturer, who must determine the most appropriate values for the product. Supplemental information can be provided if the manufacturer believes the required information to be inadequate for the product. The agency is amending § 1040.20 (b)(5) and (d)(1) to make clear and to emphasize that recommended values of "minimum use distance" and "maximum exposure time" must be provided.

19. A comment stated that the labeling required in § 1040.20, while required to be permanently affixed, is not clearly required to be legible throughout the product's useful life. A paper or plastic label may deteriorate from heat and remain permanently affixed but not be legible. Another comment suggested that any label warning should be in contrasting color to draw attention to it. The comment noted that colors for labels were not specified in § 1040.20(d), although reproductions of the labels in the instructions are explicitly "color optional."

Products subject to the performance standards promulgated under the authority of the Radiation Control for Health and Safety Act of 1968 must comply with the standards during their entire useful life. The labels required for the sunlamp product must be legible and permanently affixed. Hue, intensity, contrast, and size of the wording on a label with the background are part of the legibility concept. Reproductions in user instructions of the required labels are permitted to be in colors chosen by the manufacturer because, if the reproductions were required to be the same color as on the product, the cost of the user information brochure could be increased needlessly. The agency has clarified § 1040.20(d) regarding label specifications.

20. Several comments objected to the complexity of the summary listing of deleterious effects required by § 1040.20(f) on the ground that manufacturers should not be expected to maintain current knowledge of every possible deleterious effect from ultraviolet radiation.

The agency believes that the manufacturer of a product has an obligation to inform the user, as well as the purchaser, of the known deleterious effects associated with the product. The proposed standard contained a current list of selected known deleterious effects in § 1040.20(f) (1)(iii) and (2)(iii). However, the agency believes the simplified statements included in the warning required by § 1040.20 (d)(1)(i), (f) (1)(ii) and (2)(ii) are adequate and will be more effective; thus, § 1040.20(f) (1)(iii) and (2)(iii) are deleted.

21. One comment suggested that all ultraviolet lamps, regardless of their purpose, carry the instructions specified in § 1040.20(f)(2). This would reduce the probability that ultraviolet lamps outside the definition of § 1040.20(b)(11) might be used for tanning and would eliminate the need for a new lampholder design, permitting the present standardization of lampholder designs to be continued. Another comment suggested that a technical brochure providing complete application and safety information should be made available and packed with each six-lamp container.

The agency rejects these comments. The first suggested action is too broad; thus, the warning would be placed on lamps used in situations where no hazard to humans is posed. The purpose of the base requirement of § 1040.20(c)(6) is to force the use of ultraviolet lamps in lampholders that comply with the other requirements of the standard. Regarding the second suggestion, safety information packed with each six-lamp container would probably not be available to the user because most users in the home buy only one lamp at a time.

Manufacturers of all sunlamp products and ultraviolet lamps intended for use in sunlamp products are currently subject to the records and reports requirements under § 1002.61(a)(4). On the effective date of this final rule, those intended for skin tanning will be included automatically in § 1002.61(c)(1), which concerns products subject to standards prescribed under 21 CFR Chapter I, Subchapter J. To conform the regulations concerning records and reports, § 1002.61(a)(4) is amended to delete any reference to sunlamps and ultraviolet lamps intended to induce skin tanning.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (secs. 358 and 360a, 82 Stat. 1177–1179, 1182 (42 U.S.C. 263f and 263i)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I, Subchapter J of Title 21 of the Code of Federal Regulations is amended as follows:

1. In Part 1002 by revising § 1002.61(a)(4) to read as follows:

§ 1002.61 List of specific product groups.

(a) * * *

(4) Ultraviolet lamps and products containing such lamps intended for irradiation of any part of the living human body by light of wavelength in air less than 320 nanometers to perform a diagnostic or therapeutic function.

* * * * *

2. In Part 1040 by adding new § 1040.20 to read as follows:

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

(a) *Applicability.* The provisions of this section are applicable as specified herein to the following products manufactured on or after May 7, 1980.

(1) Any sunlamp product.

(2) Any ultraviolet lamp intended for use in any sunlamp product.

(b) *Definitions.* As used in this section the following definitions apply:

(1) "Intended" means the same as "intended uses" in § 801.4 of this chapter.

(2) "Irradiance" means the radiant power incident on a surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter (W/cm^2).

(3) "Maximum exposure time" means the greatest continuous exposure time interval recommended by the manufacturer of the product.

(4) "Maximum timer interval" means the greatest time interval setting on the timer of a product.

(5) "Minimum use distance" means the least distance from the ultraviolet lamp at which the user should be exposed to radiation from the product, as recommended by the manufacturer.

(6) "Protective eyewear" means any device designed to be worn by users of a product to reduce exposure of the eyes to radiation emitted by the product.

(7) "Spectral irradiance" means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ($W/(cm^2)$ (nm)).

(8) "Spectral transmittance" means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the proctective eyewear.

(9) "Sunlamp product" means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 180 and 320 nanometers, to induce skin tanning.

(10) "Timer" means any device incorporated into a product that terminates radiation emission after a preset time interval.

(11) "Ultraviolet lamp" means any lamp which produces radiation in the wavelength interval of 180 to 320 nanometers in air and is intended for use in any sunlamp product.

(c) *Performance requirements*—(1) *Irradiance ratio limits.* For each sunlamp product and ultraviolet lamp, the ratio of the irradiance within the wavelength range of greater than 180 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanometers through 320 nanometers shall not exceed 0.003 at any distance and direction from the product or lamp.

(2) *Timer.* (i) Each sunlamp product shall incorporate a timer with multiple timer settings adequate for the recommended exposure time intervals for different exposure distances and expected results of the product as specified in the label required by paragraph (d) of this section.

(ii) The maximum timer interval shall not exceed the recommended maximum exposure time as indicated on the label required by paragraph (d)(1)(vii) of this section, or 10 minutes, whichever is less. This requirement does not preclude a product from alllowing a user to reset the timer before the end of the preset time interval. No timer interval shall have an error greater than ±10 percent of the maximum timer interval of the product.

(3) *Control for termination of radiation emission.* Each sunlamp product shall incorporate a control on the product to enable the user manually to terminate radiation emission from the product at any time without disconnecting the electrical plug or removing the ultraviolet lamp.

(4) *Resumption of radiation emission.* When radiation emission from a sunlamp product has been terminated for any reason, including termination by a timer, resumption of such emission shall not be possible until the product is reactivated manually by the user.

(5) *Protective eyewear.* (i) Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximmum number of persons that the instructions provided under paragraph (f)(1)(iii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance of the protective eyewear required by paragraph (c)(5)(i) of this section shall not exceed a value of 0.001 over the wavelength range of greater than 180 nanometers through 320 nanometers and a value of 0.01 over the wavelength range of greater than 320 nanometers through 360 nanometers, and shall be sufficient over the wavelengths greater than 360 nanometers to enable the user to see clearly enough to read the labels and reset the timer.

(6) *Compatibility of lamps.* An ultraviolet lamp shall not be capable of insertion and operation in any of the following lampholders:

(i) "Single-contact medium screw," described in American National Standard C81.10–1976.

(ii) "Double-contact medium screw," described in American National Standard C81.10–1976.

(d) *Label requirements.* In addition to the labeling requirements in Part 801 of this chapter and the certification and identification requirements of §§ 1010.2 and 1010.3 of this chapter, each sunlamp product and ultraviolet lamp shall be subject to the labeling requirements prescribed in this paragraph and paragraph (f) of this section. All labels prescribed in this paragraph shall be permanently affixed or inscribed on an exterior surface of the product so as to be legible and readily accessible to view when the product is fully assembled for use.

(1) Each sunlamp product shall have a label which contains:

(i) The words "DANGER—Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

(ii) Designation of the ultraviolet lamp type which is to be used in the product.

(iii) A recommended minimum use distance specified both in meters and in feet (or in inches).

(iv) Directions for measuring the minimum use distance.

(v) A warning that exposure at distances less than the mimimum use distance is not recommended.

(vi) A warning to use protective eyewear whenever the product is energized.

(vii) A recommended maximum exposure time in minutes.

(viii) A recommendation for duration, frequency, and spacing of sequential exposures.

(ix) A statement of the time it may take before the expected results appear.

(2) Each ultraviolet lamp shall have a label which contains:

(i) The words "Sunlamp—DANGER—Ultraviolet radiation. Follow instructions."

(ii) The model identification.

(iii) The words "Use ONLY in fixture equipped with a timer."

(3) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§ 1010.2(b) and 1010.3(a) of this chapter, the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. When the tags or labels required by §§ 1010.2(b) and 1010.3(a) of this chapter are affixed or inscribed on the ultraviolet lamp packaging, the name of the manufacturer and month and year of manufacture required to be permanently affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the Director, Bureau of Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp.

(e) *Test for determination of compliance.* Tests on which certification pursuant to § 1010.2 of this chapter is based shall account for all measurement errors and statistical uncertainties in the measurement process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the product. The measurements shall be made under those operational conditions and procedures that maximize the emission of radiation and with the measuring instrument so positioned and so oriented as to result in the maximum detection of the radiation by the instrument. However, the measuring instrument shall be no closer to the product than the minimum use distance. Such measurements shall be made at a test voltage up to 130 root-mean-square volts if the sunlamp product or ultraviolet lamp is designed to operate from nominal 100 to 120 root-mean-square volt power sources. If the sunlamp product or ultraviolet lamp is designed to operate from a power source having some voltage other than from nominal 100 to 120 root-mean-square volts, the measurement shall be made at a voltage up to 110 percent of the maximum nominal root-mean-square voltage specified by the manufacturer for the power source.

(f) *Instructions to be provided to users.* Each manufacturer of a sunlamp product and ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for safe use, including the following technical and safety information as applicable:

(1) *Sunlamp products.* The users' instructions for a sunlamp product shall contain:

(i) A reproduction (color optional) of the label required in paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A prominently displayed statement containing the words "DANGER—Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

(iii) A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided.

(iv) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors and filters, and which will, if installed or used as instructed, result in continued compliance with the standard.

(2) *Ultraviolet lamps.* The users' instructions for an ultraviolet lamp not accompanying a sunlamp product shall contain:

(i) A reproduction (color optional) of the label required in paragraph (d)(2) of this section, prominently displayed at the beginning of the instructions.

(ii) A statement prominently displayed containing the words "DANGER—Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause eye injury and sunburn; repeated exposure may cause premature aging of the skin and skin cancer. Medications or cosmetics applied to the skin may increase your sensitivity to ultraviolet light. Consult physician before using lamp if taking any medication or if you believe yourself especially sensitive to sunlight."

(iii) A warning that the instructions accompanying the sunlamp product should always be followed to avoid or to minimize potential injury.

Effective date. This regulation shall be effective May 7, 1980.

(Sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f).)

Dated: October 30, 1979.

Jere E. Goyan,

Commissioner of Food and Drugs.

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